DETAILED ACTION

Remarks

Claims 1, 4-27, 29, 30, 32, 33, and 35-37 are allowed. Claims 2, 3, 28, 31, and 34 have been cancelled.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 28th, 2010 has been entered.

Interview Summary

Examiner discussed possible amendments to be made to the claims so as to place the claims in condition for allowance. Applicant agreed to Examiner's amendments, and Examiner agreed to have the amendments entered by way of an Examiner's Amendment.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Timothy Van Dyke on July 16th, 2010.

The application has been amended as follows:

1. (Currently amended) A method to determine whether a patient has taken a medication, comprising

providing to a patient a medication comprising a combination of at least one active therapeutic agent and an odorous compound or olfactory marker, which is not chemically part of the active therapeutic agent itself, detectable in gaseous exhaled breath, the combination to be taken by the patient as a result of the patient's own actions;

obtaining a sample of the patient's gaseous exhaled breath;

analyzing the sample of the patient's breath utilizing an electronic nose to detect said odorous compound or olfactory marker detectable in gaseous exhaled breath to ascertain the presence or absence of said marker in the patient's breath, where the presence of the odorous compound or marker is an indication that the patient has taken the medication at a prescribed time and in a prescribed dosage and the absence of the odorous compound or marker is an indication that the patient has not taken the medication at all or at a prescribed time or in a prescribed dosage; wherein the medication is to be taken by volitional patient action at specified times and in prescribed dosage; and,

based on the analysis, determining whether the patient has taken the medication or not at a prescribed time or in a prescribed dosage.

4. (Currently amended). The method of claim 1 wherein the sample of the patient's breath is analyzed to ascertain the presence or absence of said odorous compound or olfactory marker by said electronic nose which employs sensor technology selected from the group consisting of semiconductor gas sensor technology and conductive polymer gas sensor technology.

5. (Currently amended) The method of claim 4 wherein if the odorous compound or olfactory marker is present in the sample of the patient's breath, the sensor technology produces a unique electronic fingerprint which is an indication of the presence of the odorous compound or olfactory marker in the patient's breath.

6. (Currently amended) The method of claim 1 wherein the odorous compound or olfactory marker is selected from trans-Anethole (1-methoxy-4-propenyl benzene) - anise; Benzaldehyde (benzoic aldehyde) - bitter almond; Butyl isobutyrate (n-butyl 2, methyl propanoate) - pineapple; Cinnamaldehyde (3-phenylpropenal) - cinnamon; Citral (2-trans-3, 7-dimenthyl-2, 6-octadiene-1-al) - citrus; Menthol (1-methyl-4-isopropylcyclohexane-3-ol) - menthol; and alpha-Pinene (2, 6, 6-trimethylbicyclo-(3,1,1)-2-heptene) - pine.

7. (Currently amended) The method of claim 1 wherein the sample of the patient's breath is analyzed to ascertain the presence or absence of said odorous compound or olfactory marker by a spectrophotometer.

8. (Currently amended) The method of claim 1 wherein the sample of the patient's breath is analyzed to ascertain the presence or absence of said odorous compound or olfactory marker by a mass spectrometer.

9. (Currently amended) The method of claim 1 wherein the odorous compound or olfactory marker is an additive combined with the medication.

10. (Currently amended) The method of claim 1 wherein the odorous compound or olfactory marker is provided with the medication in the form of a coating on the medication.

12. (Currently amended) The method of claim 1 wherein said providing comprises providing the odorous compound or olfactory marker with said medication as a liquid.

13. (Currently amended) The method of claim 1 wherein said providing comprises providing the odorous compound or olfactory marker with said medication for the patient to take via the lungs.

14. (Currently amended) The method of claim 1 wherein said providing comprises providing the odorous compound or olfactory marker with said medication for the patient to take intranasally.

15. (Currently amended) The method of claim 1 wherein said providing comprises providing the odorous compound or olfactory marker with said medication for the patient to take intravenously.

16. (Currently amended) The method of claim 1 further comprising the step of recording results regarding the presence or absence of the odorous compound or olfactory marker as provided from the analysis of the sample of the patient's breath.

18. (Currently amended) The method of claim 1 where the analysis of the sample of the patient's breath includes comparing any odorous compound or olfactory marker sensed in the sample of the patient's breath with a predetermined signature profile of a specific odorous compound or olfactory marker.

19. (Currently amended) The method of claim 18 wherein the predetermined signature profile of a specific odorous compound or olfactory marker is associated with a specific drug.

20. (Currently amended) The method of claim 18 wherein the predetermined signature profile of a specific odorous compound or olfactory marker is associated with a class of drugs.

23. (Currently amended) The method of claim 1 wherein the odorous compound or olfactory marker is not detectable unless it first reacts with enzymes in the patient's mouth.

24. (Currently amended) The method of claim 1 wherein the odorous compound or olfactory marker is not detectable unless it first reacts with acids in the patient's stomach.

25. (Currently amended) The method of claim 1 wherein the odorous compound or olfactory marker is not detectable unless it first is absorbed in the patient's gastrointestinal tract and then is, at least partially, excreted from the lungs.

26. (Currently amended) The method of claim 1, further comprising: if it is determined that the patient did take the medication, analyzing the sample of the patient's breath to ascertain the concentration of said odorous compound or olfactory marker in the patient's breath.

27. (Currently amended) The method of claim 1 further comprising identifying a baseline odorous compound or olfactory marker spectrum for the patient at a time prior to a time at which it is desired to ascertain whether a patient has taken a medication.

29. (Currently amended) A method of producing medication which is detectable as an indication of patient compliance in taking the medication comprising the steps of:

identifying an odorous compound or detectable olfactory marker substance detectable in gaseous exhaled breath, and

combining a medication with said odorous compound or detectable olfactory marker substance, wherein said medication is to be taken by volitional patient action at specified times whereby subsequent analysis of the patient's breath will confirm the presence or absence of said odorous marker or detectable olfactory marker substance and thus indicate whether the patient has complied in taking said medication at a specified time and at a specified dosage, wherein said combining comprises ~~a step selected from the group consisting of: providing said odorous compound or marker as a coating to or~~ physically combining said odorous compound or detectable olfactory marker substance with said medication for administration in the form of pills, capsules, or fast-dissolving tablets, ~~and admixing said odorous compound or maker with said medication for administration in a liquid form selected from oral administration of a syrup or via inhalation~~ wherein said odorous compound or olfactory marker substance is present in a separate fast-dissolving compartment in the pill, capsule or tablet .

30. (Currently amended) The method of claim 1 wherein said providing comprises providing the odorous compound or olfactory marker with a medication for the patient to take transdermally.

32. (Currently amended) The method of claim 1 wherein the odorous compound or olfactory marker is a combination of odorous compounds or olfactory markers combined as an additive with the medication.

35. (Currently amended) The method of claim 1 wherein said odorous compound or olfactory marker is a Generally Recognized as Safe compound.

36. ~~(New)~~ (Previously presented) The method of claim 1 wherein the patient is alerted as to the results of said method and if the result of said method indicates non-compliance, this can be remedied.

37. (Currently amended) The method of claim 1 wherein said obtaining a sample of the patient's gaseous exhaled breath and said analyzing the sample of the patient's breath utilizing said electronic nose to detect said odorous compound or olfactory marker occurs at said patient's home or other remote location and wherein the results of said obtaining and said analyzing are transmitted via a communication means to a computer for compliance monitoring by medical staff.

Allowable Subject Matter

Claims 1, 4-27, 29, 30, 32, 33, and 35-37 are allowed.

The following is an examiner's statement of reasons for allowance: The prior art of record does not teach or fairly suggest the method to determine whether a patient has taken a medication as recited in claim 1, which includes providing a medication comprising a combination of at least one active therapeutic agent and an odorous compound or olfactory marker and analyzing a sample of the patient's breath utilizing an electronic nose to detect said odorous compound or olfactory marker in order to ascertain if the patient has or has not taken the medication at a prescribed time and a prescribed dosage. Additionally, the prior art of record does not teach or fairly suggest a method of producing medication which is detectable as an indication of patient compliance in taking the medication, as recited in claim 29, which includes that the identified odorous compound or olfactory marker is physically combined with the medication in the form of a pills, capsules, or fast-dissolving tablets, and wherein the odorous compound or olfactory marker is present in a separate fast-dissolving compartment in the pill, capsule, or tablet.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

Applicant's arguments, see pages 8-12, filed April 28th, 2010, with respect to the rejections of all the previously pending claims have been fully considered and are persuasive. The rejections of the claims have been withdrawn in view of Applicant's arguments and the amendments made, as shown above in the Examiner's Amendment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL TURK whose telephone number is (571)272-8914. The examiner can normally be reached on M-F, 9-630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT /Jill Warden/
Supervisory Patent Examiner, Art Unit 1797